DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 17 2004

The Honorable Jim Marshall
House of Representatives
Washington, D.C. 20515-1003

Dear Mr. Marshall:

Thank you for your letter of July 22, 2004, co-signed by your colleagues, to Lester M. Crawford, Ph.D., D.VM., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1)). Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

An Administrative Law Judge (ALJ) under regulations found at 21 CFR Part 12 conducts FDA's formal hearings. These regulations reflect provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act and the Administrative Procedures Act that apply to formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of new animal drug approval (NADA) 140-828, pursuant to section 512(e)(1)(B) of the FD&C Act. CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register* on October 31, 2000. Bayer filed a request for a hearing on November 29, 2000, and the Commissioner of FDA agreed, publishing a notice of hearing on February 20, 2002. Subsequently, joint stipulations and revised joint stipulations were submitted on September 20 and December 24, 2002, respectively. Documentary evidence and written direct testimony was submitted by CVM on December 9, 2002, and by Bayer and the Animal Health Institute (AHI) on December 13, 2002. Oral hearing for cross-examination of witnesses was held between April 28 and May 27, 2003. Briefs were filed on July 18, 2003, and reply briefs on August 15, 2003. The initial decision of the ALJ was issued on March 16, 2004, and the parties filed exceptions to the initial decision on May 17, 2004. On July 16, 2004, CVM filed its reply to the Bayer and AHI exceptions, and Bayer and AHI filed their reply to CVM's exceptions.

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A public docket (00N-1571) was established at the time the NOOH was published in October 2000. Documents related to the hearing, including the NOOH, referenced scientific studies, correspondence, briefs, the initial decision of the ALJ, and subsequent filings by CVM and Bayer and AHI can be found in the public docket.

Thank you again for contacting us about this matter. We hope this information is helpful. If we can be of further assistance, please let us know. An identical letter has been sent to the co-signers of your letter.

Sincerely,

Patrick Ronan
Assistant Commissioner
for Legislation

cc: Docket Management Division
(Docket No. 00N-1571)